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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,655	08/16/2005	Sitke Aygen	P70594US0	6168

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EXAMINER	
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ART UNIT	PAPER NUMBER
3735	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/535,655	AYGEN, SITKE	
	Examiner	Art Unit	
	PATRICIA C. MALLARI	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-11 and 17-21* is/are rejected.

7)☒ Claim(s) *12-16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *5/19/05* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/17/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This is a final Office action. Any new grounds of rejection were necessitated by the applicants' amendments to the claims.

Information Disclosure Statement

The information disclosure statement filed 4/17/08 has been considered. The non-patent literature citations have been crossed out because they were already considered in the information disclosure statement filed 6/24/05.

Claim Objections

Claim 17 is objected to because of the following informalities:

On line 3 of claim 17, "increase of $^{13}CO_2$ in the exhaled air of a subject according to claim 12" should be replaced with "induced release of $^{13}CO_2$ according to claim 12, wherein the measured induced release of $^{13}CO_2$ is an increase of $^{13}CO_2$ in the exhaled air of the subject".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 17 recites "a previously measured increase of $^{13}CO_2$ in exhaled air of a healthy subject to the same measuring used for the exhaled air of the subject". The instant specification, as originally filed, lacks sufficient support or written description of the "a previously measured increase of $^{13}CO_2$ in exhaled air of a healthy subject". The instant specification does describe, "A reduced metabolization is indicated by a deficiency of pancreatic enzymes as seen by a delayed or reduced release of $^{13}CO_2$ as compared to healthy subjects, thus allowing a reliable diagnose". However, this description fails to indicate when the increase of $^{13}CO_2$ in exhaled air of the healthy subject was measured or what measuring technique is used (wherein the examiner can only guess the meaning of he latter part of line 6-line 7 of claim 17; see rejection under 35 U.S.C. 112, 2nd paragraph).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 recites, "to the same measuring used for the exhaled air of the subject". It is unclear what is meant by this limitation, particularly with respect to the rest to the rest of the limitation recited on lines 5-7 of claim 17, thereby rendering the claim indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 8 is rejected under 35 U.S.C. 102(b) as being anticipated by "Exocrine pancreatic insufficiency: accuracy and clinical value of the uniformly labeled ^{13}C-Hiolein breath test" by Lembcke et al. Lembcke teaches a method for inducing release of $^{13}CO_2$ in exhaled air comprising intravenous administration of secretin and oral administration of a ^{13}C-triglyceride to a subject (see pp. 669 and 670 of Lembcke).

Claims 8, 9, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by "Comparative Clinical Evaluation of the ^{13}C-Mixed Triglyceride Breath Test as an Indirect Pancreatic Function Test" by Löser et al. Löser teaches a method for inducing release of $^{13}CO_2$ in exhaled air comprising intravenous administration of secretin and oral administration of a ^{13}C-triglyceride to a subject (see entire document, especially pp.328-329 of Löser).

Regarding claim 9, the ^{13}C-triglyceride is the mixed triglyceride 1,3-distearyl, 2 (carboxyl-^{13}C) octanoyl glycerol (see entire document, especially p. 328 of Löser), wherein 1,3-distearyl, 2 (carboxyl-^{13}C) octanoyl glycerol) is also referred to as glyceryl-1,3-dioctadecanoate-2-octanoate-1-^{13}C.

Regarding claim 11, 200 mg of the mixed triglyceride was orally administered with a test meal (see entire document, especially p. 328 of Löser).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lembcke, as applied to claim 8, and further in view of "Comparative study of pancreatic polypeptide (PP) secretion, endocrine and exocrine function, and structural damage in chronic alcohol inducted pancreatitis (CAIP)" by Mee et al. Lembcke teaches the intravenous administration comprising intravenously administering to the subject 1 clinical unit of secretin per kilogram of body weight (see entire document, especially p. 670 of Lembcke), but is silent as to the time period over which the administration occurs. However, Mee discloses a secretin-pancreozymin test wherein 1 U/kg body weight of secretin was administered to the subject over two minutes (see entire document, especially p. 643 of Mee). Therefore, it would have been obvious to one of

ordinary skill in the art at the time of invention to use the administration time of Mee as that of Lembcke, since Lembcke admits to administering 1 U/kg body weight of secretin, and Mee discloses 2 minutes as an appropriate time for such administration, 2 minutes being well within 15 or 30 minutes.

Response to Arguments

The applicants did not provide any arguments as to newly presented claims 8-21 that are relevant to the rejections made above.

Allowable Subject Matter

Claims 12-16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: Regarding claims 12-16, the primary reason for allowance is the inclusion of measuring the release of $^{13}CO_2$ in the exhaled air of the subject before and after intravenous administration of secretin, in combination with all of the other limitations of the claims, which is not found in the prior art.

In light of the multiple rejections under 35 U.S.C. 112, 1st and 2nd paragraphs, no statement of allowability is being given at this time with respect to claims 17-21. Upon resolution of these rejections, the prior art will be revisited. See MPEP 2173.06.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent Application Publication No. 2003/0228647 to Asuka et al. discloses a method wherein secretin is intravenously administered to the body. Asuka further discloses determining an increase in concentration of $^{13}CO_2$ in the breath after administration of a ^{13}C-labelled triglyceride (see entire document, especially paragraphs 3, 12, and 13 of Asuka).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PATRICIA C. MALLARI whose telephone number is

(571)272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia C. Mallari/
Examiner, Art Unit 3735